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Comparison of interface pressures in two dynamic pressure ulcer prevention supports (NIMBUS 3 and SUMMIT): A randomized controlled trial

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Conflict of Interest

None

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Abstract

Background: Pressure ulcers are a risk for bedridden patients and various supports exist to prevent them. The Pressure Relief Index (PRI) evaluates pressure relief of dynamic mattresses over time. This study compared the PRI of the SUMMIT mattress (AKS-France) and the NIMBUS 3 (HNE Medical).

Methods: In this non-blinded, randomized, crossover, non-inferiority study, patients aged ≥ 60 with a BMI of 16-35 kg/m², predominantly confined to bed, able to walk with aid and with pelvic symmetry were recruited from a hospital rehabilitation department from March-April 2012. Exclusion criteria included past or present pressure ulcers, inability to remain supine and deep vein thrombosis. Peak pressures of the sacrum were recorded at 0.1 Hz during a single complete 10-minute inflating cycle on both mattresses, with the order determined via electronic randomization allocation.

Results: Thirty-one subjects were included and randomized; with 14 finally analyzed in the SUMMIT-NIMBUS 3 order group and 16 in the NIMBUS 3-SUMMIT group. The difference in PRI < 30 mmHg between the two mattresses was 13.2% [0.3 – 26.1] ($p < 0.05$), allowing a non-inferiority - superiority switch. The SUMMIT mattress demonstrated a significantly higher percentage of time < 30 mmHg ($p = 0.0454$). No significant difference in mean minimal pressure was seen ($p = 0.3231$) and mean maximal pressure was in favor of SUMMIT mattress ($p = 0.0096$). BMI did not affect pressure profile. There were no adverse events.

Conclusions: Evaluated by the PRI, the SUMMIT mattress had a better interface pressure profile than the NIMBUS 3 in older patients. The PRI is a promising tool for clinical decision-making and research, warranting validation.

Keywords: Pressure ulcer, alternating pressure air mattress, prevention

. Introduction

Pressure ulcers are a common, painful, debilitating and expensive condition in Western societies [1]. According to the National Pressure Ulcer Advisory Panel (NPUAP), pressure ulcers are a consequence of pressure associated with shearing applied to the skin in an intense and/or prolonged way [2]. Reducing pressure applied to the skin is one of the prevention measures usually recommended (ANAES, 2001, National Pressure Ulcer Advisory Panel, 2014). This can be achieved by regularly alternating the patient's posture or by using a support that reduces interface pressure. Supports that reduce interface pressures can be either static supports made of deformable material, or dynamic supports operating discontinuously or continuously. Supports that decrease the interface pressure, such as constant low-pressure support or alternating pressure air mattresses, have been shown to prevent the onset of pressure ulcers in comparison with a standard mattress (Grade 1 evidence) [3]. Studies on the effectiveness of these supports are rare and have a low level of evidence, both regarding the incidence [4] and treatment of pressure ulcers [5]. Thus, in general practice, the choice of support is arbitrary and most often based on the criteria of comfort or handling, or personal experience or beliefs.

No air support has demonstrated superiority over other static prevention supports for the prevention of pressure ulcers, even in a recent large randomized controlled study (2029 patients) [6, 7] or when comparing different air supports [8]. However, the incidence of pressure ulcers is too rare to show any difference on limited or large samples [7, 9]. One large randomized controlled study (1972 subjects) did not find any difference in the incidence of pressure ulcers between an air mattress and an air mattress overlay, although a potential difference could have been missed due to the high cut-off applied to detect a difference (50% reduction) [4]. No consensus has been reached on the cost-effectiveness of these supports [7, 10].

Indirect criteria to measure the risk of pressure ulcer such as interface pressure have been proposed by different authors [11]. Rithalia et al. developed a Pressure Relief Index (PRI) to evaluate the effectiveness of a mattress-type support with alternating pressure based on the principle that pressure ulcer formation depends on both interface pressure and the duration of pressure application. The PRI is calculated as the ratio of the time during which the interface pressure is below a given threshold over the total time of one mattress cycle and is commonly expressed as a percentage of the mattress cycle [12]. As pressure ulcer occurrence is a poorly feasible outcome measure for studies on the effectiveness of the static supports for prevention, PRI represents a good alternative.

The aim of this study was to compare two dynamic air mattresses, using the PRI as the main outcome measure in a population of older people. We hypothesized that the PRI <30mmHg measured on the SUMMIT mattress (AKS-France) would not be higher than that of the NIMBUS 3 (HNE medical).

2. Materials and methods

2.1 Trial design and ethical approval

This was a non-inferiority crossover randomized study. A non-inferiority trial was conducted to show that ulcer prevention supports (NIMBUS 3) is not worse than the control (SUMMIT) by a predefined non-inferiority margin in terms of the primary outcome (the alternative hypothesis, H_1). The corresponding null hypothesis (H_0) is that the NIMBUS 3 is indeed worse than the SUMMIT by more than or equal to the non-inferiority margin. These definitions directly contrast superiority trials, which test the null hypothesis that neither ulcer prevention support arm has superior clinical efficacy.

The crossover design means that each patient tests both prevention support ulcers in the study in a randomized order of placement (NIMBUS 3 then SUMMIT or SUMMIT then NIMBUS 3).

This study was approved by the institutional human investigation committee (Comité de Protection des Personnes, CPP Sud-Méditerranée III, France,) and prospectively registered on clinicaltrials.gov (NCT01402765) and the European registry EudraCT (2011-A00697-34). Participants were included in the trial upon providing written informed consent.

2.2 Participants

Patients were recruited at ****BLINDED**** Physical Medicine and Rehabilitation department, France. Criteria for eligibility were age 60 or over, a BMI of 16 to 35 kg/m², confined to their bed for at least 12 hours/day, able to walk with aid and with pelvic symmetry. Patients with cognitive impairment, asymmetrical deformation of the spine or the hips in the frontal plane, past or present pressure ulcers or the inability to remain supine were excluded. Any patients who were retracting consent or suffering from progressive cardiovascular pathology or those with deep vein thrombosis or with life expectancy <24 weeks were also excluded.

2.3 Intervention

SUMMIT (AKS-France) and NIMBUS 3 (HNE medical) single-sized mattresses were placed in a research room with constant temperature (between 23°C and 26°C) and switched on for 45 minutes

before experiments. Subjects were asked to wear only thin clothes without seams, buttons or zippers on the sacrum area to avoid artificial high pressure points. They were asked to lie down on their back with their arms at their sides and legs extended, directly on the pressure mapping system (X3, XSensor Technology Corporation, Calgary, Canada) which completely covered the mattresses. Subjects were positioned so that the sacrum area was centered on the air cells of the mattresses.

Before each measurement, the sensors (1.6 cm² each) were calibrated from 10 to 220 mmHg according to the manufacturer's recommendations. Peak pressures were recorded at 0.1 Hz during a single complete inflating cycle (10 minutes) on the sacral area, after 5 min of stabilization of inflation pressures. Adding the weight of a subject to the mattress requires a new pressure balance between the different cells of the mattress. We chose a stabilization duration of 5 minutes because no duration recommendation is specified by the manufacturer.

Data were collected with dedicated software (X3 medical v6.0, Xsensor technology) and results were expressed using 10 mmHg blocks converted as a percentage of total time. The investigators were not blinded to the support used, but the data were collected automatically, without the investigators' intervention. The percentage of time spent with peak pressures per threshold of 10 mmHg were calculated (PRI) and the minimum and maximum interface pressures were recorded. A threshold of 30 mmHg was used as the alterations of skin perfusion are described between 20 and 40 mmHg on sacral skin in healthy subjects [12, 13].

2.4 Outcomes

The primary objective of this study was to show that the SUMMIT support was not inferior to NIMBUS 3 support in terms of skin pressure of the sacrum region as assessed by the PRI (% time with PRI <30 mmHg). Secondary objectives included the mean, maximum and minimum interface pressure measurements (mmHg). In the original protocol, the percentage of time where the pressures were changing (%) and patient tolerance of the mattress (yes/no) were planned secondary objectives, but these were not recorded as the assessment of the mattress tolerance was decided to be irrelevant given the short exposure time, and the percentage of time when the pressures changed could not be measured on dynamic mattresses.

2.5 Sample size calculation

Based on preliminary results on three patients, the mean percentage of time with a PRI <30 mmHg was 93% with NIMBUS 3 and 87% for SUMMIT. The absolute difference between the two supports for time with a PRI <30 mmHg was 0% for the first two patients and 7% for the third one. Based on a 15% non-inferiority threshold for the absolute difference of PRI <30 mmHg between the two supports, the number of subjects needed was 35 (alpha risk 0.05, power 0.8).

2.6 Randomization

Subjects were positioned successively on both mattresses using a crossover design. The sequence NIMBUS – SUMMIT or SUMMIT – NIMBUS was randomly assigned using computer-generated random numbers created by the methodologist at the Biostatistics Department of ** BLINDED** using a 1:1 randomization ratio and size blocks of 4 to 6. The random allocation sequence was centralized on an online application which recruiting investigators could log onto with a password.

2.7 Statistical methods

All statistical analyses were performed using SAS © (SAS Institute, Cary, NC) version 9.3. Statistical results were expressed as mean (standard deviation) (SD) or median with 25th and 75th percentiles according to the distribution. The numbers and associated percentages were given for categorical variables. The two supports were compared with a non-inferiority design using the Schuirmann two one-sided tests for the percentage of time <30 mmHg and a linear mixed model was used to adjust on the BMI of each patient. Maximum and minimum pressures were compared using a paired Student test. The absence of a sequence effect due to the order of mattresses used was verified before each test. All statistical tests were conducted as 0.05 type 1 error rate for one- and two-sided tests.

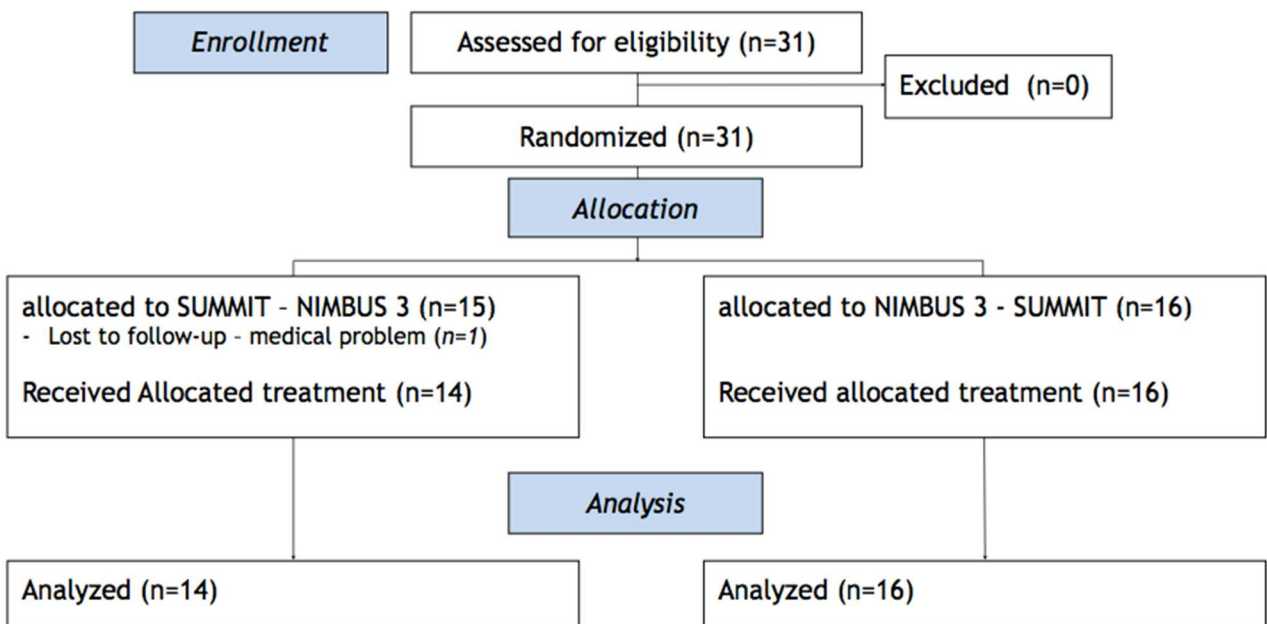
3. Results

Thirty-one patients were included and randomized from March 27 to 11 April 2012. The median age was 79 +/- 9 years and median BMI was 27 +/- 6 kg/m² (Table 1). Twenty-two (71%) participants were female. Patients were evenly distributed between the SUMMIT-NIMBUS group (S-N order, n=15) and the NIMBUS-SUMMIT (N-S order; n=16). One patient in the S-N group did not complete the trial because the patient's condition changed, rendering them ineligible following randomization. (Figure 1). Two subjects with a BMI >35 kg/m² were included. These participants were retained in the analysis as the mattresses have a maximum weight limit of 150kg and the maximum weight recorded in our population was 95kg. We performed an ancillary analysis to assess the impact of BMI on the primary outcome. The PRI values are shown in Figure 2. We calculate a power of 74% in regards to 30 participants for primary outcome.

Figure 1: Flow Chart

| | | | |
|--------------------------|------------------------------|--------------------------------|---------------|
| Population | SUMMIT – NIMBUS 3 N=14 | NIMBUS 3 - SUM- MIT N=16 | Total N=30 |
| Sex ratio M/F | 6/8 | 2/14 | 8/22 |
| Age (years) | 80 (9) | 78 (9) | 79 (9) |
| BMI (kg/m ²) | 27 (6) | 28 (6) | 27 (6) |

Table 1: Population characteristics. Data are expressed as means (SD) or medians [25th percentile - 75th percentile].



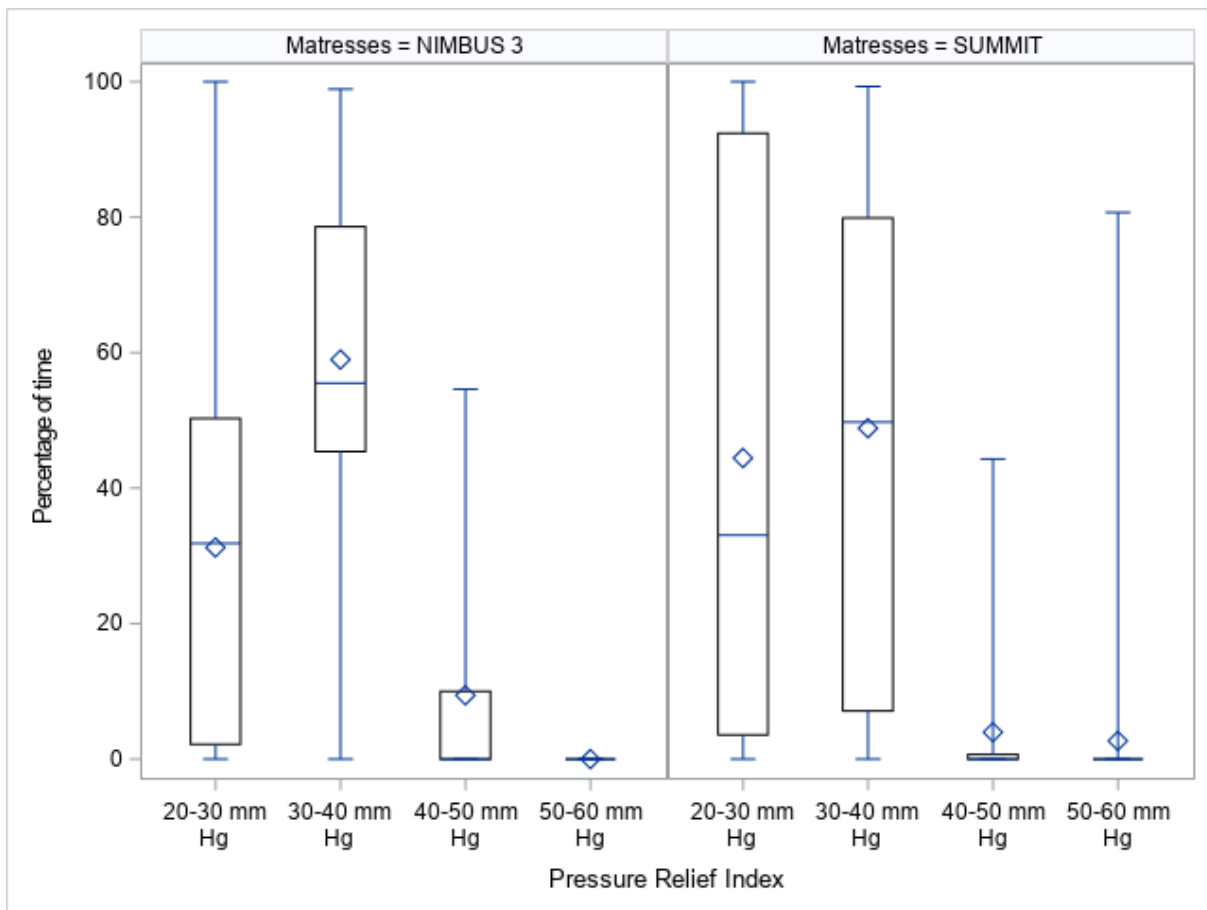


Figure 2: Boxplots of Pressure Relief Index for both mattresses; where horizontal lines represent medians, diamonds represent means, boxes denote IQR and whiskers show range.

3.1 Primary outcome

The mean percentage of time <30 mmHg was 31.24% (SD 28.25) with NIMBUS 3 and 44.46% (SD 39.57) with SUMMIT. The median difference between the two mattresses was 13.2% [0.3 – 26.1] ($p < 0.0001$). The measurement sequence did not influence PRI results ($p = 0.8358$). The Schuirmann test gave a p -value < 0.001 , allowing us to reject the null hypothesis. Therefore, for a PRI <30 mmHg, SUMMIT is not inferior to NIMBUS 3 by more than 15%. As the difference in PRI <30 mmHg was greater than 0, we were able to perform a non-inferiority - superiority switch. A Student paired test showed that the percentage of time with a PRI <30 mmHg was significantly higher with SUMMIT mattresses ($p = 0.0454$).

3.2 Secondary outcomes

No significant difference in minimal pressure was observed between mattresses ($p=0.3231$), yet a significant difference of maximal pressure between the two mattresses was seen ($p=0.0096$) (Table 2).

| | NIMBUS | SUMMIT | SUMMIT-NIMBUS difference | P value |
|----------------------------|--------------|--------------|-----------------------------|---------|
| Minimum pressure (mmHg) | 15.11 (1.94) | 14.89 (2.16) | -0.22 (1.20) | 0.3231 |
| Maximum pressure (mmHg) | 18.25 (2.15) | 17.43 (2.53) | -0.82 (1.63) | 0.0096 |

Table 2: Median minimum and maximum pressure of the two mattresses

An ancillary analysis was made to estimate the impact of BMI on the percentage of time with a PRI <30 mmHg with mixed linear modeling. There is no influence of BMI on PRI (Table 3). No adverse events were recorded.

| Factor | Estimate | Standard deviation | p-value |
|----------|----------|--------------------|---------|
| NIMBUS 3 | -13.2167 | 6.3212 | 0.0457 |
| SUMMIT | 0 | | |
| BMI | -0.1184 | 1.0107 | 0.9076 |

Table 3: Mixed linear model results of effect of BMI on PRI

4. Discussion

This study shows that the SUMMIT mattress has a better pressure relief profile than the NIMBUS 3 mattress. The percentage of time spent with a PRI <30 mmHg evaluated on one cycle is higher and the average maximum pressure values are lower.

The majority of pressure measurement comparisons between air mattresses have been made on young, healthy subjects and under laboratory conditions [12]. However, the usual profile of patients at risk of pressure ulcers is different. These patients are in an acute clinical condition requiring prolonged bed rest and much older; in France more than one in three hospital stays concerns people over 65 years' old [14]. The population of this study (older, not very mobile, confined to bed >12 hours per day) more closely reflects the conditions of usual prescriptions of pressure ulcer prevention support in healthcare services. Several factors such as hypomobility (impaired mobility) and undernutrition leading to amyotrophia [15] expose older people to these risks, in addition to physiological aging, which weakens the skin barrier [16].

Studies on the effectiveness of static or dynamic supports using the criterion of the onset of pressure ulcers are most often of low scientific evidence [3]. The main problem is the low incidence of pressure ulcers (estimated at 14/1000 patient-days in a high-risk population in nursing homes) [17] requiring a large population, which is rarely reached [3]. Even when large randomized trial are performed, the cost of these studies can be a limitation to achieve sufficient recruitment to obtain a meaningful result given this low incidence [7]. Although necessary and complementary to the approach proposed in this study, the cost and duration of carrying out large randomized studies does not allow to consider the evaluation of all the different mattresses existing on the market, each having different technologies, evolving with the advances of research and development.

It would be unfeasible to perform this type of study for every mattress on the market. A new criterion that can measure a potential risk of the onset of pressure sores is necessary. Reducing the pressure between a support and the skin is a key factor, present in all the recommendations for the prevention of pressure ulcers [2]. High pressure values are associated with the development of pressure ulcers [18] and with greater tissue deformations, although the relationship is not linear [19]. Furthermore, high pressure is associated with a drop in micro vascularization assessed by transcutaneous oxygen tension (TcPO₂) [20] and this hypo vascularization is associated with the development of pressure ulcers [21].

The use of interface pressure measuring devices in clinical practice dates back to the early 1980s [22]. Several pressure measurement criteria have been described such as pressure peak, dispersion index, pressure peak index and contact area [23]. However, these measurements can only be applied to a constant-low pressure support and the time factor is not addressed. The aim of a dynamic support is to obtain transient but repeated pressure relief from pressure on one zone by alternating the air pressure in different compartments of the mattress known as ‘cells’. The alternating inflation and deflation progress through cycles. The notion of pressure application time is important for this preventive support [24]. Currently, the PRI is the only measurement criterion applicable to alternating pressure air supports. However, this measurement has not been validated and its metrological characteristics are unknown. It is currently the only objective measurement to address a skin risk factor (pressure) and consider the exposure time.

Our results are consistent with other studies that found PRI <30 mmHg values ranging from 33.3 to 57.6% depending on the mattress [12]. Approximately half the time spent on the SUMMIT mattress exposes the skin to pressure >30 mmHg, compared to two-thirds for the NIMBUS mattress. Thus, the SUMMIT mattress has a lower interface pressure. Although it is premature to conclude on prevention of the risk of pressure ulcers, these results provide a measurable decision criterion in favor of the SUMMIT mattress.

This study had several limitations: first, we limited measurement to one complete cycle for each mattress (10 minutes), but there is no previous publication on reproducibility of PRI. Performing several cycles could have been useful to evaluate reproducibility of this measure. We also did not assess the tolerance and comfort of the mattress, but the very short exposure time to the mattresses would not have provided clinically relevant data.

We included two subjects with a BMI > 35 kg/m² contrary to the inclusion criteria. However, this deviation from the protocol allowed us to perform an ancillary analysis showing that the BMI did not influence the PRI measurements. This will aid study design for future trials, allowing the inclusion of participants with a greater range of BMI. In future studies, weight rather than BMI should be used to determine the inclusion criteria, in accordance with the maximum weight recommended by mattress manufacturers. Another limitation was that the number of subjects included was less than the calculated sample size. Nevertheless, as a significant difference was demonstrated, the power of the study was sufficient.

We made a conscious choice to consider interface pressure as the only criterion for comparing pressure ulcer prevention supports, excluding other factors such as shear forces, deep tissue deformation and maceration. Measuring these other factors would be complex and expensive, and is beyond the

scope of this study [25]. The recent literature does not show frequent use of pressure interface and PRI for bedsore prevention mattresses evaluation, but we believe that objective measures are necessary and should be applied in preference to large and expensive studies evaluating rare pressure ulcer events. Although Landis appointed the value of 32 mmHg as the cut-off for ischemia [26], this cut-off may not be the same *in vivo* or for all populations. There are probably variations related to vascular and tissue quality that change with age and co-morbidities. We used a pressure mat to measure pressure, however this tool has been criticized due to its potential hammock effect [27, 28]. The results were derived from the dynamic interaction between the patient and the support and may provide information for potential further extrapolation. However, this technique should be tested for long-term reliability. Finally, the experiments were conducted in 2012 and mattress technologies have evolved since then; it would be interesting to use a similar methodology to assess new devices available on the market.

5. Conclusion

This study found that, assessed by PRI, the SUMMIT mattress had a better interface pressure profile than the NIMBUS 3 mattress when used in an older population hospitalized for follow-up care and rehabilitation. Objective measurement of the improved SUMMIT mattress pressure measurements in this population may help to choose the right support in pressure ulcer prevention.

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